DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

g1887a

September 24, 2001

WARNING LETTER
SJN-01-17

Certified Mail
Return Receipt Requested

Mr. David Schuster
President
Saint Croix Dairy Products, Inc.
40000 Sion Farm, Christiansted
St. Croix, VI 00820

Dear Mr. Schuster:

On May 31 and June 1, 2001 the Food and Drug Administration (FDA) conducted an inspection of your dairy plant located at 40000 Sion Farm, Christiansted St. Croix, VI 0Q820. Review of the inspectional information and labels for your milk products found that the products are adulterated within the meaning of sections 402 (a)(4) of the Federal Food Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), parts 110.40 (f); 110.80 (a) (2); and 110.80 (a)(5) as follows:

1. There is no assurance that the raw materials used at your dairy firm do not contain levels of microorganisms that may produce foodborne or other diseases in humans, and/or that they are pasteurized or otherwise treated during the manufacturing operation to assure that they do not contain microorganisms that would cause the product to be adulterated within the meaning of the act. [21 CFR Part 110.80 (a)(2)]

2. No testing of incoming raw milk is made to assure it does not contain antibiotics [21 CFR Part 110.80(a)(1).

3. Failure to demonstrate that the thermometers or devices being used during your manufacturing operation to monitor the process are accurate and adequately maintained. The inspection revealed that the following thermometers or devices have not been calibrated: indicating thermometer (mercury in glass) and temperature recording device used for the HTST pasteurizer, the dial thermometers used in the raw milk storage tank, the dial thermometers used in the cold holding tank for pasteurized products and the thermometer used for the finished products storage coolers and freezers. In addition, during our inspection some thermometers were not working properly. Assurance that the products are adequately processed is dependent on the accuracy and reliability of these monitoring devices.

In addition, failure to have a recording temperature device to assure that the raw milk inside the bulk storage tank is constantly maintained under control temperature conditions to prevent the growth of undesirable microorganisms in the product. During the inspection the FDA investigator was informed that the milk received may remain in a storage tank for more than 24 hours. Also a 4°F difference between a calibrated thermometer used by the FDA Official and a dial thermometer used in the storage tank was observed and reported. [21 CFR Part 110.40 (f); and 110.80 (a)(5)]

4. Failure to have adequate procedures in place to assure that the equipment used to manufacture or that may become in contact with the dairy products manufactured are maintained in a manner to prevent contamination. The inspection revealed no protective caps were observed on that three of the four in-lets that connect the raw milk storage tank with the transportation truck washing nozzle of the cleaning-in-place washing station were not capped or protected. [21 CFR Part 110.40 (a)]

You should take prompt action to correct this deviation and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Additionally, on August 31, 2001, during an inspection and meeting held between you and the FDA San Juan District Office management, you informed the FDA that you sell milk to interstate carriers such as cruise lines and airlines. It is your responsibility to assure that the pasteurized milk introduced into interstate carriers by your firm is in compliance with the Grade A Pasteurized Milk Ordenance and therefore, received from a facility included in the Interstate Milk Shipper (IMS) list as a Grade A milk plant.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step being taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Carmelo Rosa, Acting Compliance Officer.

Sincerely,

Mildred R. Barber

Mildred R. Barber
District Director